Date: 20080815

Docket: T-575-08

Citation: 2008 FC 950

Ottawa, Ontario, August 15, 2008

PRESENT: The Honourable Mr. Justice Zinn

BETWEEN:

PFIZER CANADA INC., PFIZER LIMITED and PFIZER RESEARCH AND DEVELOPMENT COMPANY, NV/SA

Applicants

and

PHARMASCIENCE INC. and THE MINISTER OF HEALTH

Respondents

REASONS FOR ORDER AND ORDER

[1] This is an appeal by the Applicants under Rule 51 of the *Federal Courts Rules* of the Order of Prothonotary Aalto dated June 27, 2008, dismissing the Applicants' motion for further production of documents.

Background

[2] On February 6, 2008, Pharmascience filed a submission for a notice of compliance with the Minister in respect of amlodipine mesylate 5 and 10 mg tablets (the Pharmascience Product).

Pharmascience, in its submission, compared the Pharmascience Product, in part, to Pfizer's Norvasc 5 and 10 mg tablets, which contain amlodipine besylate.

[3] Pharmascience characterizes its submission as a new drug submission (NDS); however, the certification by the Minister of the date of filing of the submission states that Pharmascience has submitted an abbreviated new drug submission (ANDS), not a NDS. Pharmascience says that the Minister's certificate is in error in its characterization of its submission.

[4] Section 5(1) of the *Patented Medicines (Notice of Compliance) Regulations* (PM (NOC) Regulations) requires that a notice of allegation (NOA) be served when "the submission directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted". On February 22, 2008, Pharmascience served a NOA on Pfizer with respect to Canadian Patent Nos. 1,321,393 (the '393 Patent) and 2,170,278 (the '278 Patent) which are listed on the Patent Register.

[5] On April 10, 2008, Pfizer filed an application in this Court under s.55.2 (4) of the *Patent Act* and under the PM(NOC) Regulations for an order prohibiting the Minister of Health from issuing a notice of compliance to Pharmascience in respect of the Pharmascience Product until after the expiry of the '393 Patent and the '278 Patent.

[6] On April 22, 2008, Pharmascience filed a Notice of Motion to dismiss Pfizer's application pursuant to subsections 6(5)(a) and (b) of the PM (NOC) Regulations on the bases that the '393 Patent for the besylate salt of amlodipine is not infringed by the Pharmascience Product, that the '278 Patent is not infringed by the Pharmascience Product, and that the '278 Patent is not eligible for inclusion on the Patent Register with respect to amlodipine besylate tablets.

[7] In letters dated May 5, 2008 and May 29, 2008, Pfizer sought production of a number of documents related to Pharmascience's drug submission. Some documents were provided, however, Pfizer alleges that the information provided by Pharmascience was not sufficient to address all of the issues raised in its notice of application and, by Notice of Motion dated June 18, 2008, Pfizer sought an order for the production of the following documents:

(a) all correspondence (including email) between Health Canada and Pharmascience in connection with its submission for its proposed amlodipine mesylate tablets;

(b) proposed package labelling;

(c) the Quality Overall Summary in its entirety and relevant sections of Module 3, which include:

(i) 3.2.P.2 Pharmaceutical development including all dissolution tests and dissolution profiles generated to compare the Pharmascience Product with the Pfizer Norvasc® product;

(ii) 3.2.P.5.1 Drug product specifications;

(iii) 3.2.P.5.4 Batch analyses (signed and dated certificates of analyses) of all manufactured lots, including all lots used in pharmaceutical equivalence testing (both test and reference products);

(d) all clinical study report(s): bioequivalence and comparative bioavailability studies with corresponding comprehensive summary – bioequivalence templates (cs-be templates);

(e) clinical study report(s): other relevant studies including safety and efficacy studies performed in patients (not in healthy volunteers) and literature review;

(f) all toxicology data generated in support of both the active pharmaceutical ingredient, the formulated powder and the Pharmascience Product;

(g) the Form V submitted by Pharmascience in Module 1;

(h) The Annotated Product Monograph for amlodipine mesylate, which is included in Module 1; and

(i) the HC 3011 Form entitled “Drug Submission Application Form” included in Module 1.

[8] Pfizer submits that the information requested was relevant, necessary, and important to clarify the type of drug submission made by Pharmascience and to determine the extent to which the Minister may have erred in permitting Pharmascience to file an ANDS when the Pharmascience Product does not contain an identical medicinal ingredient to the Norvasc product to which it compares itself, or in permitting Pharmascience to file a NDS when it does not contain all of the

information required for such. Pfizer argues that these issues arise from its notice of application, the relevant portions of which are as follows:

> 4. In the Pharmascience Letter, Pharmascience asserts that it has filed a new drug submission (NDS) in respect of the Pharmascience Product. This assertion is not correct.
>
> 5. The Minister's certificate attached as Schedule "A" to the Pharmascience Letter indicates that Pharmascience has submitted an Abbreviated New Drug Submission (ANDS), not an NDS. In any event, Pharmascience seeks to obtain an NOC by comparing the Pharmascience Product against NORVASC® on the basis of demonstrating bioequivalence to NORVASC®. (emphasis added)
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> 6. The Minister is not entitled to permit Pharmascience to compare the Pharmascience Product to NORVASC®. In light of the applicable Food and Drug Regulations and on the basis of Health Canada's Policy entitled "Interpretation of 'Identical Medicinal Ingredients'", Pharmascience's proposed tablets are not bioequivalent to, and do not contain the "identical medicinal ingredient" to NORVASC®.

[9] Prothonotary Aalto dismissed Pfizer's motion for production with costs on the basis that the information sought was not relevant, necessary, and important for the purposes of Pfizer's application or its response to the motion to dismiss.

[10] The Prothonotary was of the view that the thrust of Pfizer's position was an attempt to review the actions of the Minister. He held that the issues to be determined in the proceedings were those set out in the NOA. The NOA issues are issues of infringement and validity. As the documents requested did not deal with those issues, the Prothonotary was of the view that they were not relevant, necessary, or important, and the order sought was denied.

Issues

[11] Pfizer submits that the Court in this appeal ought to consider its motion for production *de novo* because the issue of the production of the requested documents is vital to the final issues in this litigation or alternatively, because the Prothonotary clearly erred in concluding that it is the NOA that defines the issues to be determined in the proceedings under the PM(NOC) Regulations when, it is submitted, it is the notice of application, the originating pleading, that sets out the issues to be determined.

Analysis

Are the documents requested vital to the final issue of the case?

[12] In *Merck & Co., Inc. v. Apotex Inc.*, [2004] 2 F.C.R. 459 (C.A.), the Federal Court of Appeal set out the standard of review of discretionary orders made by a Prothonotary. It directed that the first question to be addressed is whether the question is vital to the final issue.

> ... [A] judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would now read: "Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless: (a) the questions raised in the motion are vital to the final issue of the case, or (b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts."

In *Canada v. Aqua-Gem Investments Ltd.*, [1993] 2 F.C. 425 (C.A.), at para. 97, MacGuigan J.A. described questions that are vital as “questions vital to the final issue of the case, i.e. to its final resolution”.

[13] Pfizer submits that the question of whether these documents are to be produced is vital. It argues that the Prothonotary, in effect, determined that Pfizer had no standing to raise the issue of the correct characterization of Pharmascience's submission which it set out in its notice of application, and thus disposed of a question vital to the final issue of the case.

[14] One of the facts alleged by Pfizer in its pleading is that Pharmascience claims to have filed an NDS whereas the Minister has described it as an ANDS. It is perhaps worthy of note that those facts do not appear to be in dispute. However, as is evident from Pfizer's pleading and in particular from paragraph 5 of its application, reproduced above, the proper characterization of Pharmascience's submission is not vital to the issue raised by Pfizer. Rather, the proper characterization of Pharmascience's submission is a factual question that, at best, relates to an issue Pfizer advances as to whether the Pharmascience submission may properly compare the Pharmascience Product to Norvasc. That issue is not dependant on nor determined by the resolution of whether the submission is a NDS or an ANDS. No submission was made by Pfizer that the documents requested are critical to determine the issue of whether the Pharmascience Product may be compared to Norvasc.

[15] Accordingly, as the question determined by the Prothonotary was not vital to the final issue of the case, a review *de novo* is warranted only if the Prothonotary's Order was clearly wrong, in the sense that it was based upon a wrong principle or upon a misapprehension of the facts.

Was the Prothonotary's Exercise of Discretion based on a wrong principle?

[16] Pfizer submits that the Prothonotary's Order was based on a wrong principle in that he erred in law when he concluded that "it is the Notice of Allegation that defines the issues to be determined in the proceedings under the Regulations". Pfizer submits that it is its notice of application that defines the issues to be determined. It further submits that this error by the Prothonotary led him to make two additional errors: First, that the issues to be determined in the motion to dismiss are only those raised by Pharmascience in its notice of motion when, in fact, Pharmascience is seeking to strike out the proceeding in its entirety, and secondly, that he erred in characterizing the documents requested as being directed towards the safety and efficacy of the Pharmascience Product.

[17] In my view, the Prothonotary made no such error of law. The Federal Court of Appeal in *G.D. Searle & Co. v. Novopharm Ltd.*, [2008] 1 F.C.R. 529, 2007 FCA 173, at para. 33, held that "the NOA defines the issues to be determined in proceedings under the *Regulations*". It was previously observed by the Court of Appeal in *Mayne Pharma (Canada) Inc. v. Aventis Pharma Inc.*, 2005 FCA 50, at paras. 20 and 21, that this is so because of the scheme set out in the PM(NOC) Regulations:

> The scheme established by the Regulations is unusual. Section 6(2) of the Regulations provides that the Court "shall make an order... in respect of a patent which is the subject of one or more allegations if it finds that none of those allegations is justified". The allegations are framed by the respondent (the second person) but the application for prohibition is brought by the first person, the patent holder. Consequently, the patent holder must frame its application so as to demonstrate that none of the allegations made by the second person is justified. It may be that there are other grounds for holding that the sale of the subject medicine would infringe the patent(s) but the first person is forced to deal with the allegations made in the detailed statement.

> If the applicant patent holder must plead to the grounds raised in the detailed statement, even though other grounds of infringement may exist, it is patently unfair to allow the respondent to raise different grounds of infringement in its evidence in reply to the application for prohibition. The respondent, the second person, sets the parameters of the dispute in its detailed statement. It cannot then change those parameters after the applicant for prohibition, the first person, has framed its application to address the issues raised by the detailed statement.

[18] Accordingly, the Prothonotary was correct in asserting that the NOA defines the issues to be determined in the proceeding. Those are issues of validity and infringement and it was not suggested by Pfizer that the documents requested were relevant, necessary and important to those issues.

[19] It follows, in my view, that the Prothonotary's observations concerning the relevance of the information requested for the purposes of the motion and his comments concerning safety and efficacy (which were based on responses of Pfizer's affiant given on cross-examination) are not in error.

[20] For the reasons above, I find that the question determined by the Prothonotary was not vital to the final issue in the case and his Order was not clearly wrong. As a result, the Order of the Prothonotary ought not to be disturbed and the motion is dismissed.

ORDER

THIS COURT ORDERS that:

1. This motion is dismissed.

2. The Applicants shall pay to the Respondent, Pharmascience Inc., the sum of $2,000.00 inclusive of GST for costs forthwith.

"Russel W. Zinn"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-575-08
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